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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,406	03/17/2004	Thomas Weisel	SUSI.PAU.02	5563

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EXAMINER
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NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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11/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/803,406

Applicant(s)

WEISEL ET AL.

Examiner

TUAN V. NGUYEN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,7,13,15 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,13,15 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/22/08</u> | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 11, 2008 has been entered.

***Amendment***

2. According to the Amendment filed on June 11, 2008, claims 6 and 10 have been canceled. Accordingly, claims 1, 5, 7, 13, 15, and 19-21 are pending in this present application and they are presented for examination.

***Allowable Subject Matter***

3. The indicated allowability of claims 10, 13, 15 and 19-21 is withdrawn in view of the newly discovered reference(s) to Hart et al. (US 5,569,269). Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 1, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toy et al (US 5,618,290) in view of Trott (US 5,312,422) and further in view of Hart et al. (US 5,569,269).**
7. Toy et al disclose a device (1, Figures 2-12) comprising: a hollow elongate shaft (11); a handle assembly (16 and 17) coupled to the shaft (11) wherein the handle assembly (16 and 17) is also a needle lock and having a releasable locking relationship with the needle; a thumb slide (17) moveable on the handle housing in a proximal and distal position relative to the needle assembly creating a free suture state when distal and a captured/locked state when proximal; an actuating rod (3, Figure 4) having a proximal end and distal end; a needle assembly (6, 7, 8, 9) disposed at the distal end of rod (3) movable back and forth with the actuating rod between an extended and retracted state; the needle assembly having unitary

(clearly shown where 3 points in Figure 4) cylindrical bifurcated portions (backing arm 9 and gathering arm 7) defining a suture slot between; the arms (7, 9) are separate due to spring forces in the extended state and proximate/contacting due to shaft (11) in the retracted state; the needle assembly also comprising a sharp distal tip (6) integral with arm (7) (see col. 3, line 20 to col. 4, line 25). With respect to the limitation "the backing arm and gathering arm of the needle assembly being unitary with one another at a proximal end of the suture slot", Toy discloses the needle shaft 3 or actuating rod, the pointed head 6 or sharp distal tip, the hook 8, and the latch 9 or gathering arm, bifurcated portions, which is located between the shoulder or hook 8, latch 9 or gathering arm and the bottom portion of needle shaft that connected to the sharp needle tip 6 or the backing arm, are fabricated from a single piece of 174-PH grade stainless steel (see col. 4, lines 33-36). With respect to the limitation "the bifurcated portions having a proximate and spaced relationship when the needle assembly is in the retracted state", Toy discloses the gathering arm is created by two cuts that perpendicular to each other thereby forming a L-shaped groove 7 (see col. 4, lines 40-50), thusly, Toy discloses that some material will be removed by the cutting operation thereby there will be a small gap between the gathering arm and the backing arm when the needle assembly is in the retracted state.

8. Toy discloses the invention substantially as claimed except for clearly discloses the distal portion of the gathering arm extending proximally from the sharp distal tip to form a hook. However, Trott disclosed such a feature on his suturing needle.

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Trott discloses a suturing needle (see Figs. 4 and 5) comprising: needle assembly 14 having a recess 44 or bifurcated portion near its distal end 32 wherein the recess 44 is adjacent and abutting hook 46 for capturing the suture (see col. 3, lines 50-68). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the hook, as disclosed by Trott, to the needle, as disclosed by Toy in order to gain the advantage of providing a positive suture locking mechanism before the needle is fully in retracted state as suggested by Trott.

9. Toy as modified by Trott discloses the invention substantially as claimed except for the proximal portion of the gathering arm includes an inward bend near its distal end and wherein the distal end of the proximal portion of the gathering arm in a partially retracted position of the needle assembly is bent toward and contacts the backing arm proximally of the distal portion of the gathering arm and opens the passage.
10. However, Hart discloses a suturing needle having the ability for snaring suture comprising (Fig. 63), among other things, a needle 504 and wire-like elements 402 wherein one wire-like element 402 may be resides within a projection of the area enclosed by the hook of the other wire-like element during closure (col. 16, lines 1-8). Apparently, the advantage is providing a positively capturing means for the surgeon to capture suture and secure the suture before the needle is completely in the full retracted position. It would have been obvious to one of ordinary skill in the art to incorporate a bend as disclosed by Hart to the proximal arm portion of the gathering arm 9 of Toy's needle so that it too would have the same advantage.

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11. **Claims 13, 15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toy et al (US 5,618,290) in view of Trott (US 5,312,422).**
12. Toy et al disclose a device (1, Figures 2-12) comprising: a hollow elongate shaft (11); a bifurcated needle assembly (6, 7, 8, 9), which defining a suture slot, disposed at the distal end of rod (3) movable back and forth with the actuating rod between an extended and retracted state; the needle assembly also comprising a sharp distal tip (6) integral with arm (7); a handle assembly (16 and 17) coupled to the shaft (11) wherein the handle assembly (16 and 17) is also a needle lock and having a releasable locking relationship with the needle; a thumb slide (17) moveable on the handle housing in a proximal and distal position relative to the needle assembly creating a free suture state when distal and a captured/locked state when proximal; an actuating rod (3, Figure 4) having a proximal end and distal end (see col. 3, line 20 to col. 4, line 25). Toy discloses the invention substantially as claimed except for a needle housing lock is pivotal on the handle housing between an unlocking position and a locking position.
13. However, Trott discloses a suturing needle (see Figs. 1, 8 and 9) comprising: a needle assembly 14 attached to an elongated handle 2. The elongated handle 2 comprises a thumb slide assembly 6, 4 coupled to the needle assembly 14 and movable longitudinally on the handle housing between a distal position and a proximal position; a needle lock included an extension member 58 with a cantilever end 60 and detent 64, wherein the cantilever end is pivotal on the handle between an unlocking position (Fig. 8) and a locking position (Fig. 9) (col.

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4, lines 45-68). Apparently, the advantage of the handle of Trott's device is to provide a positive locking mechanism to needle assembly. Therefore, it would have been obvious to one of ordinary skill in the art to replace Toy's handle with the handle, as disclosed by Trott, in order to gain the advantage of providing a positive suture locking mechanism as suggested by Trott.

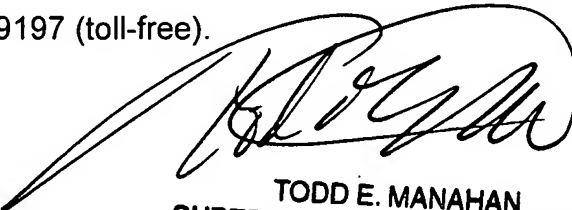
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731



TODD E. MANAHAN  
SUPERVISORY PATENT EXAMINER